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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,507	06/19/2000	Horst Peschel	4070-174US (K400417US)	3984

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AKIN GUMP STRAUSS HAUER & FELD L.L.P.
ONE COMMERCE SQUARE
2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103

EXAMINER

HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/596,507

Applicant(s)

PESCHEL, HORST

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 86-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 86-107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendment filed 1/18/05 has been entered.
2. The objection to claim 52 under 37 CFR 1.75(c), as being of improper dependent form is withdrawn due to the cancellation of this claim.
3. The rejection of claims 44-49, 51-53, 63, 70-78 & 83-84 under 35 U.S.C. 112, first paragraph, as containing new matter is withdrawn due to the cancellation of these claims.
4. The rejection of claims 44-49, 51-53, 63, 70-79 & 83-84 under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of "partially differentiated" is withdrawn due to the cancellation of these claims.
5. Applicant's arguments filed 1/18/05 have been fully considered but they are not persuasive.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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7. Claims 104-106 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record for cancelled claim 79 in Paper NOs: 9 (mailed 4/9/02), 12 (mailed 11/05/02), 16 (mailed 7/21/03) & 20040712, and as follows.

No proper antecedent basis remains for the recitation “(b) not sufficient to eliminate capability of the treated cells to perform mitosis”; thereby, still constituting new matter. It is again noted that Applicants have never addressed where conception of this additional method step was described within the specification.

8. Claims 104-106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons made of record in Paper NOs: 9 (mailed 4/9/02) & 12 (mailed 11/05/03), 16 (mailed 7/21/03) & 20040712, and as follows.

The second recitation of the term “differentiating-promoting factor” is not defined in the claims, in which this term is not limited to the recited Markush group. In other words, no universal differentiating-promoting factor exists nor would all cells encompassed by the claims reasonably express receptors to all such putative factors (if known), as previously made of record.

It is suggested that amending claim 104 (line 9) to “contact with [the] said differentiation-promoting factor” should obviate this rejection.

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9. Claims 104-107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reason made of record for canceled claims 79 & 83-84 in Paper No: 20040712, and as follows.

Claims 104 & 107 need to be rewritten to convey clearly what Applicant is attempting to claim. As previously made of record, phrases like “tissue made by transiently contacting in vitro i) neuronal progenitor cells...”, or “tissue made by transiently contacting in vitro... ii) a differentiation-promoting factor...”, or “for a period of time that is (a) sufficient to make treated, determined cells that will differentiate... with one of (1) differentiation induced... and (2) transplantation, and (b) not sufficient ...” (e.g., as it relates to claim 104); or “and that will differentiate... upon subsequent treatment... with one of (1) in vitro differentiation induced by..., and (2) in vivo transplantation, and express a receptor....” (i.e., as it relates to claim 107) make little or no sense.

Claim 105 also makes no sense by the recitation of “wherein the neuronal tissue is *further* made by selecting and proliferating a single treated, determined cell...” when the neuronal tissue is already made in base claim 104... by transiently contacting... neuronal progenitor cells....”.

It is also suggested that claims 86, 93 & 94 recitation of “upon subsequent treatment... with one of (1) in vitro differentiation induced by..., and (2) transplantation” be rewritten, and that the “determined cells” be changed to “primed cells” to more clearly reflect Applicant’s invention.

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10. Claims 86-107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reason made of record for canceled claims 79 & 83 in Paper No: 20040712, and as follows.

As previously made of record, the recitation of “substantially” is a relative term that is indefinite, because it is unclear when something is alternatively no longer “substantial”. In other words, the term “substantially only” in claims 86, 93, 94, 104 & 107 is a relative term which renders the claim indefinite. The term “substantially only” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

11. Claims 86-107 are rejected under 35 U.S.C. 102(b) as being anticipated by Boss et al. (US Patent 5,411,883; IDS Ref #3), for the reasons made of record for cancelled claims 44-49, 51-53, 63, 70-79 & 83-84 in Paper NOs: 9 (mailed 4/9/02), 12 (mailed 11/05/03), 16 (mailed 7/21/03) & 20040712, and as follows.

In contrast to Applicant’s assertions on page 13 of the response, as previously made of record, Boss clearly teach neuronal progenitor cells, and partially differentiated/determined neural progenitor cells/neuronal tissue, derived from the ventral “mesencephalon”/midbrain, as illustrated by Boss’ claim 1, in which Boss’ neuronal progenitor cells further “differentiate into *substantially* only dopaminergic neurons”, as illustrated in columns 17-18 & 19-20, and as previously made of record. Thus, Applicant’s arguments remain clearly not on point with that claimed, because it remains immaterial what properties the different product of a terminally

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differentiated dopaminergic neuron possesses, because this is not what the pending rejection is based upon. The issue is simple. A different method used to produced the **claimed product** does not change the product. Neuronal progenitor cells are neuronal progenitor cells. Neuronal progenitor cells treated with the same differentiation factors (i.e., primed/determined neuronal progenitor cells), as recited in the claims, are neuronal progenitor cells treated with the same differentiation factors (i.e., primed/determined neuronal progenitor cells), and possess identical properties. Boss clearly teach partially differentiated/determined/primed neuronal progenitor cells, as well as their differentiated progeny, as extensively made of record, in which no “immune response” is observed when implanted into their host. It is noted that Applicant’s assertion that “Boss claims cells that can divide *at most* eight times, severely limiting the potential for sub-cloning and continued life of the cultures” has no basis in fact, and is a mischaracterization of Boss’ teachings (even though such arguments are irrelevant, because the current claims (i.e., a product) are not directed to methods “severely limiting the potential for sub-cloning”, but to a product taught by Boss). Again, Applicant’s arguments remain not on point with the pending rejection, for the reasons extensively made of record; which remain consistent with that held by the U.S. courts in *Ex parte Gray*, *In re Best*, *In re Thorpe* and *In re Marosi*, previously made of record. As previously made of record,

“the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved”. *Ex parte Gray*, 10 USPQ 2d 1922 (1989); *In re Best*, 195 USPQ 430 (CCPA 1976).

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12. Claims 86-107 are rejected under 35 U.S.C. 102(b) as being anticipated by Emory University/Luskin et al. (WO 97/02049; IDS Ref #10), for the reasons made of record for cancelled claims 44-49, 51-53, 63, 70-79 & 83-84 in Paper NOs: 9 (mailed 4/9/02), 12 (mailed 11/05/03), 16 (mailed 7/21/03) & 20040712.

In contrast to Applicant's assertions on pages 13-14 of the response, as previously made of record, Luskin et al clearly teach isolation of human and mammalian brain-derived neuronal progenitor cells capable of differentiating into >90% dopaminergic neurons. It is noted that even though the lateral ventricles (i.e., openings within the brain) may be argued to border the cerebral hemisphere, Luskin's anterior subventricular zone is below the cerebral hemisphere. Therefore, no one skilled in the art would argue that the SVZa is in the cerebral hemisphere. Nevertheless, the issue remains that such product-by-process limitations do not change the characteristics of the **claimed product** consisting essentially of neuronal progenitor cells that were treated/determined/primed to eventually differentiate in dopaminergic neurons, for the reasons extensively made of record; which remain consistent with that held by the courts in *Ex parte Gray*, *In re Best*, *In re Thorpe* and *In re Marosi*, previously made of record.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
June 1, 2005

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PATENT EXAMINER


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